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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,854	03/07/2002	Felix Kratz	25048/20	6344

7590 11/14/2007
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Greenville, SC 29603

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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11/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/009,854		KRATZ, FELIX	
	Examiner		Art Unit	
	Jeffrey E. Russel		1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-50 is/are pending in the application.
- 4a) Of the above claim(s) 38 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,37,39-41 and 43-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Applicant's election of the species in the reply filed on November 13, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 38 and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 13, 2003.

2. Claims 39, 41, and 48 are objected to because of the following informalities: At claim 39, line 2, "space" should be changed to "spacer". At claim 41, line 4, "pyrimidine" is misspelled. At claim 48, line 1, "medicament" is misspelled. Appropriate correction is required.

3. Instant claims 36, 37, 39-41, and 43-50 are deemed not to be entitled under 35 U.S.C. 119(a)-(d) to the benefit of the filing date of the German Patent Application 19926475.9, because the German Patent Application, under the test of 35 U.S.C. 112, first paragraph, does not disclose medicaments in which the drug is a diagnostically active substance; does not disclose a pharmaceutical which is an antibiotic, analgesic, or virostatic; does not disclose a cytostatically pharmaceutically active substance which is a calicheamicin or a maytansinoid; does not disclose a thiol binding group which is a vinylcarbonyl group, an aziridine group, a disulfide group, or an acetylene group; does not disclose a spacer molecule which is an aliphatic carbon ring having 3 to 12 carbon atoms; does not disclose medicaments for the purpose of treating mammals; and does not disclose diagnostic kits.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claims 36, 37, 39-41, and 43-50 are rejected under 35 U.S.C. 102(a) as being anticipated by the Kratz et al article (J. Med. Chem., Vol. 43, pages 1253-1256). The Kratz et al article teaches treating albumin with dithiothreitol so that approximately one mole sulfhydryl group (from Cys34) per molecule of albumin is obtained. The treated albumin is then reacted with the doxorubicin derivative of Figure 1. The doxorubicin derivative of the Kratz et al article has the same structure as Applicants' elected species. The pure conjugate has a drug:albumin ratio of approximately 0.9:1. See, e.g., page 1254, column 1, second full paragraph. With respect to instant claim 32, while the Kratz et al article does not intend to administer the pure conjugate in vivo to animals with cancer (instead, the Kratz et al article intends to administer the doxorubicin derivative of Figure 1 in vivo, where it reacts with endogenous albumin), an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art. With respect to instant claims 33 and 34, the pure conjugate of the Kratz et al article is deemed to anticipate the instant kit claims, whose only recited element is the carrier-drug conjugate.

6. Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being obvious over the Kratz et al article (J. Med. Chem., Vol. 43, pages 1253-1256). Application of the Kratz et al article is the same as in the above rejection of claims 36, 37, 39-41, and 43-50. To the extent that the Kratz et al article might not teach its conjugate in kit form, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to package the conjugate of the Kratz et al article in kit form because kits are routinely used in the pharmaceutical and chemical assay arts for purposes of storage, transportation, measurement, and administration.

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7. Applicant's arguments filed October 5, 2007 have been fully considered but they are not persuasive.

The examiner has reviewed the translation of the German Patent Application 19926475.9 submitted by Applicant on October 5, 2007. However, as set forth in section 3 above, the translation does not show that the currently claimed invention was disclosed in the priority document. Accordingly, the instant claims are not entitled under 35 U.S.C. 119(a)-(d) to the benefit of the filing date of the German Patent Application, and the Kratz et al article (J. Med. Chem., Vol. 43, pages 1253-1256) remains available as prior art against the instant claims under 35 U.S.C. 102(a). See MPEP 201.15, especially page 200-98, column 2, third paragraph (Rev. 5, August 2006).

Applicant may wish to review MPEP 715.01(b)(I) for a possible alternative for showing that the Katz et al article is not available as prior art under 35 U.S.C. 102(a).

Applicant may wish to correct the dependencies of withdrawn claims 38 and 42, consistent with the change in claim numbering discussed by the examiner in the previous Office action. This will expedite rejoinder and allowance of the claims should the independent claim be found allowable and the election of species requirement withdrawn.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

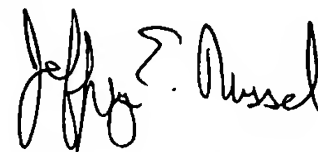
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel
November 8, 2007